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510(k) SUMMARY

ADSIS LTD.'s REMOTE PRESENCE AND CARE SYSTEM 5000

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

ADSIS Ltd.
Rechov Yad Harutzim 4
Kfar Saba, Israel 44641
Phone: 9729-766-8094
Facsimile: 9729-766-8099

Contact Person: Irving Levy

Date Prepared: November 26, 2000

Name of Device and Name/Address of Sponsor

ADSIS Remote Presence and Care System 5000

Rechov Yad Harutzim 4
Kfar Saba, Israel 44641
Phone: 9729-766-8094
Facsimile: 9729-766-8099

Common or Usual Name

Powered Communication System

Classification Name

Not Applicable

Predicate Devices

American Telecare Aviva Systems
Aerotel Heart 400

Intended Use

The **RPCS 5000** is intended to be used for transmitting medical information between a patient at a remote location and a medical worker at a central station. The **RPCS 5000** is indicated for use in short term monitoring where

Technological Characteristics and Substantial Equivalence

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SUMMARY OF TECHNICAL DEVICE DESCRIPTION AND SPECIFICATIONS

The RPCS 5000 is designed to allow a medical practitioner to remotely monitor a patient's ECG, Blood Pressure, and Weight during an interactive video conferencing session with the patient.
The system is divided physically between two locations, one part of the system is located in the patient's home, and the other part of the system is located at a central station. Information is passed between the two locations via a high-speed common carrier communication line.

The **RPCS 5000** is substantially equivalent to the other currently marketed **American Telecare Aviva Systems and the Aerotel Heart 400** which are referenced above. The **RPCS 5000** and its predicate devices are all **telemedicine systems**. Thus, the **RPCS 5000** raises no new issues of safety or effectiveness.

Performance Data

Performance tests were performed by an authorized outside agency on the Physiochair, the ECG, the NIBP, and the Scale. In all instances, the **RPCS 5000** functioned as intended and the results observed were as expected.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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ADSIS Ltd.
c/o Mr. Jonathan S. Kahan
Partner
Hogan & Hartson LLP
Columbia Square
555 Thirteenth Street, NW
Washington, DC 20004-1109

Re: K010791
Trade Name: ADSIS Ltd. Remote Presence and Care System 5000
Regulation Number: 870.2920
Regulatory Class: II (two)
Product Code: 74 DXH
Dated: March 15, 2001
Received: March 15, 2001

Dear Mr. Kahan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification

submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4645. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

The **RPCS 5000** is intended for use as a short term monitoring device, whereby a medical practitioner can communicate with a patient from a remote location and monitor a patient's ECG without analysis, blood pressure, Pulse, and weight between visits to the doctor. The system is intended to be used by a patient capable of seating himself in a chair and applying an NIBP cuff on his arm.

Division of Cardiovascular & Respiratory Devices
510(k) Number K010791

Prescription Use Only